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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,243	12/22/2005	Clara Lucia Garcia-Rodenas	3712036.00694	6067
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K&L Gates LLP				
P.O. Box 1135				
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EXAMINER				
GANGLÉ, BRIAN J				
ART UNIT		PAPER NUMBER		
1645				
NOTIFICATION DATE		DELIVERY MODE		
08/15/2011		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary**Application No.**

10/562,243

Applicant(s)

GARCIA-RODENAS ET AL.

Examiner

Brian J. Gangle

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15, 16 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 12, 13, 15, 16, 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ ~~Copies of the certified copies of the priority documents have been received in this National Stage~~
application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 4/5/2011.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment and remarks, filed 6/1/2011, are acknowledged. Claim 11 is amended. Claims 17-18 are cancelled. New claims 21-23 are added. Claims 1-13, 15-16, and 19-23 are pending.

Claims 1-10, 12-13, 15-16, and 19-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/17/2008.

Claims 11 and 21-23 are currently under examination.

Information Disclosure Statement

The information disclosure statement filed on 4/5/2011 has been considered. A signed copy is enclosed.

Terminal Disclaimer

The terminal disclaimers filed on 6/1/2011 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of applications 12/593,462, 12/593,457, 12/532,021, and 12/532,056 have been reviewed and are accepted. The terminal disclaimers have been recorded.

Claim Rejections Withdrawn

The rejection of claims 11 and 17-18 under 35 U.S.C. 102(b) as being anticipated by Haschke *et al.* (WO 01/64225 A1, 2001), is withdrawn in light of applicant's amendment thereto.

The rejection of claims 11 and 17-18 under 35 U.S.C. 102(b) as being anticipated by Giffard *et al.* (WO 03/041512 A1, 5/2003), is withdrawn in light of applicant's amendment thereto.

The provisional rejection of claims 11 and 17-18 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-7 of copending Application No. 12/593,462 is withdrawn in light of the terminal disclaimers filed on 6/1/2011.

The provisional rejection of claims 11 and 17-18 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-7 of copending Application No. 12/593,457 is withdrawn in light of the terminal disclaimers filed on 6/1/2011.

The provisional rejection of claims 11 and 17-18 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-7 of copending Application No. 12/532,056 is withdrawn in light of the terminal disclaimers filed on 6/1/2011.

The provisional rejection of claims 11 and 17-18 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-7 of copending Application No. 12/532,021 is withdrawn in light of the terminal disclaimers filed on 6/1/2011.

The rejection of claims 17-18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn. The cancellation of these claims renders the rejection moot.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brassart *et al.* (US Patent Application Publication 2002/0127211, 2002) in view of Birch *et al.* (Am. J. Clin. Nutr., 75:570-580, 2002).

The instant claims are drawn to methods for inducing a pattern of gut barrier maturation in an infant similar to that observed with breast-feeding, comprising administering to the infant a nutritional composition comprising arachidonic acid (ARA) and/or docosahexanoic acid (DHA), a non-digestible oligosaccharide comprising a milk-derived oligosaccharide and at least one organism selected from the group consisting of *Bifidobacterium* CNCM I-2168, *Bifidobacterium* CNCM I-2169, *Bifidobacterium* CNCM I-2170, *Lactobacillus johnsonii* CNCM I-1225, *Lactobacillus paracasei* CNCM I-2116, *Bifidobacterium lactis* ATCC 27536, and *Bifidobacterium longum* BB536.

Brassart *et al.* disclose methods where by a nutritional composition comprising *Lactobacillus* CNCM I-1225, milk (of various animal and plant types), and various oligosaccharides such as fructo-oligosaccharides is administered (see paragraphs 0022, 0030-0031 and 0039). The composition can be in the form of an infant formula or fermented milk (see paragraph 0044). As the nutritional composition is in the form of infant formula, it is clearly intended to be administered to infants (see claim 7).

Brassart *et al.* differs from the instant invention in that they do not disclose the inclusion of ARA or DHA in the nutritional composition.

Birch *et al.* discuss the benefits of supplementing infant formula with DHA and ARA. Birch *et al.* showed that higher plasma concentrations of DHA and ARA led to better visual acuity and stereoacuity (see abstract). They also showed that DHA and ARA supplementation of infant formula is well tolerated and beneficial to the maturation of the visual cortex in term infants (see final paragraph, page 579).

It would have been obvious to one of ordinary skill in the art, at the time of invention, to add DHA and/or ARA to the infant formula of Brassart *et al.* because such supplementation is beneficial to the maturation of the visual cortex in term infants.

One would have had a reasonable expectation of success because Birch *et al.* demonstrated a benefit of supplementation of infant formula and there is no reason that one of ordinary skill in the art would expect the infant formulas disclosed in Brassart *et al.* to alter the results found by Birch *et al.*

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is rendered indefinite by the phrase “at least one microorganism selected from the group consisting of *Bifidobacterium* CNCM I-2168, *Bifidobacterium* CNCM I-2169, *Bifidobacterium* CNCM I-2170, *Lactobacillus johnsonii* CNCM I-1225, *Lactobacillus paracasei* CNCM I-2116, *Bifidobacterium lactis* ATCC 27536, and *Bifidobacterium longum* BB536 and combinations thereof.” It is not clear how one microorganism can be a combination of microorganisms unless one is referring to a genetically engineered version where portions of the above organisms have been combined. However, such a combination is not discussed in the specification. Therefore, it appears that what applicant really intends is that the composition

contain a combination of the listed strains rather than containing a microorganism that is a combination of the listed strains. If this is the case, the claim already recites "at least one microorganism" so there is no need to mention further combinations.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 10-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/
Examiner, Art Unit 1645
/N. M. MINNIFIELD/
Primary Examiner, Art Unit 1645